IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

THE CITY OF HUNTINGTON, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, et al., Defendants.	Civil Action No. 3:17-01362 Hon. David A. Faber
CABELL COUNTY COMMISSION, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, et al., Defendants.	Civil Action No. 3:17-01665 Hon. David A. Faber

REPLY MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION FOR JUDGMENT ON PARTIAL FINDINGS REGARDING PROXIMATE CAUSATION

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INTRODUCTION

Plaintiffs' Opposition proceeds from a mistaken legal premise, fails entirely to address a critical argument made by Defendants, and depends in large part on factual assertions that are entirely unsupported by record evidence. In short, Plaintiffs' Opposition demonstrates that Plaintiffs have not satisfied their burden of proving proximate causation and that Defendants are entitled to judgment on partial findings under Rule 52(c).

The Opposition is predicated on the erroneous notion that Plaintiffs need ***only*** establish foreseeability in order to meet their burden of proving proximate causation. That assertion is belied by two decisions from courts in this District—*Employer Teamsters* and *City of Charleston*—applying the common law of West Virginia to hold that a "direct injury" is required for proximate causation. Plaintiffs do not even attempt to argue that they have satisfied this burden. Nor could they, given that the FDA-approved medicines that Defendants deliver to DEA-registered and State-licensed pharmacies would sit on a shelf, causing harm to no one, but for the subsequent actions of multiple independent third-parties, including (1) DEA-registered and State-licensed licensed doctors, (2) DEA-registered and State-licensed pharmacists, (3) criminal drug diverters, and (4) illicit drug users. This alone is dispositive and requires that judgment be entered in Defendants' favor.

Plaintiffs likewise fail meaningfully to dispute a key proposition established in the record and explained in Defendants' brief—*i.e.*, that wholesale distributors are not responsible for diversion that takes place from the medicine cabinet, well after drugs have left the closed system of distribution. The evidence shows that (1) the vast majority of the diversion that occurred in Cabell/Huntington and nationwide was diversion from the medicine cabinet, such as when a patient sells or gives away unused pills, *see, e.g.*, 6/9 Tr. (Rannazzisi) at 141:3–10 (testifying that it was the official position of the government that the most frequent method of obtaining a

pharmaceutical controlled substance for non-medical use was from friends or family), and (2) according to both Plaintiffs' own expert and the former head of DEA's Office of Diversion Control, wholesale distributors have neither the ability nor any duty to prevent that form of diversion, *see, e.g.*, 5/26 Tr. (Rafalski) at 198:19–23 ("Q. You agree that when a prescription is legitimately written and dispensed, distributors have no control over what happens to it after that point? A. That's a correct statement."); 6/9 Tr. (Rannazzisi) at 143:16-23 (agreeing that medicine cabinet diversion occurs even when "the distributor does what they're supposed to do"). This failure is fatal to Plaintiffs because—with the sole exception of a pharmacy that Defendants did not service (A-Plus Care Pharmacy in Barboursville)—the ***only*** form of diversion in Cabell/Huntington established in the record is this medicine cabinet diversion.

Finally, Plaintiffs attempt to establish causation by asserting that Defendants' supposed regulatory failures to maintain effective controls foreseeably led to diversion in Cabell/Huntington. This argument not only fails entirely to establish proximate causation; it also fails as a matter of fact based on the undisputed record evidence. Tellingly, nowhere in the Opposition do Plaintiffs cite any record evidence showing that diversion occurred at any of Defendants' customers in Cabell/Huntington—let alone that a Defendant knew or should have known about that diversion. Nor do Plaintiffs contest the undisputed evidence showing that, by no later than 2008, all suspicious orders were blocked and could not have been diverted.

In an attempt to obscure these fatal defects, Plaintiffs instead spend pages and pages establishing the point—not meaningfully in dispute—that diversion ***can*** occur if a DEA registrant fails to maintain effective controls against diversion. But that is plainly not enough. To show that a Defendant was a substantial factor in causing a public nuisance in Cabell/Huntington, Plaintiffs must show—at an absolute minimum—that the Defendant improperly shipped opioids to a

pharmacy that was engaged in diversion. Because Plaintiffs have not even arguably done that, Defendants are entitled to judgment on these facts, even putting aside their inability to establish proximate causation.

ARGUMENT

Plaintiffs are wrong about the law and the facts. Their arguments therefore do nothing to overcome Defendants' showing that they are entitled to judgment on partial findings under Rule 52(c).

I. PLAINTIFFS ARE WRONG ABOUT THE LAW.

Plaintiffs make several legal arguments, all of which are either incorrect or attack straw men. None is sufficient to prevent a defense judgment.

Foreseeability. Plaintiffs' principal legal argument is that they need not prove that Defendants' conduct was a direct cause of the alleged injuries underlying Plaintiffs' claims. Indeed, Plaintiffs all but concede that Defendants are entitled to judgment under the directness standard. Instead, Plaintiffs assert that they need only prove that Defendants' wrongdoing "substantially and foreseeably contributed to the opioid epidemic harms that plague Cabell and Huntington." Opp. 1; *see also id.* at 2 ("proximate or legal causation is assessed based upon the reasonable foreseeability of the harms to a defendant"). Plaintiffs are mistaken.

Defendants agree that Plaintiffs must prove foreseeability as part of their burden to prove proximate causation. But Plaintiffs are wrong to assert that foreseeability is the ***only*** requirement for establishing proximate causation under West Virginia law. As the West Virginia Supreme Court of Appeals has acknowledged, actionable conduct "which renders a defendant liable for damages must be a proximate, ***not a remote***, cause of injury. . . ." *Metro v. Smith*, 146 W.Va. 983,

990, 124 S.E.2d 460, 464 (1962).[1] Accordingly, Plaintiffs are simply wrong to assert that the direct injury requirement—*i.e.*, the requirement that a defendant's conduct be more than a "remote" cause of the plaintiff's injury—is not a component of West Virginia law, or that the separate requirement of "foreseeability" completely displaces it.

Contrary to Plaintiffs' suggestion, moreover, it was precisely this West Virginia law that two courts from this District recently applied in holding that the plaintiffs' claims were too remote to establish proximate causation as a matter of law. In *Employer Teamsters v. Bristol Myers Squibb Co.*, 969 F. Supp. 2d 463, 475 (S.D. W. Va. 2013), Judge Chambers held—applying West Virginia law—that the plaintiffs had failed to plead proximate causation because "a vast array of intervening events, including the 'independent medical judgment' of doctors," stood between the defendants' alleged misrepresentations regarding the medicines they manufactured and the plaintiff's alleged harm. Plaintiffs do not even attempt to argue that the same is not true here, where the FDA-approved medicines that Defendants distribute to DEA-registered pharmacies would sit on a shelf, causing harm to no one, but for the intervening medical judgments of State-licensed doctors to write a prescription and of State-licensed pharmacists to dispense those medicines to the patient. And, here, the causal chain is even longer than in *Employer Teamsters* because harms from diversion do not result unless someone diverts the medication (a crime) and someone misuses the medication (also a crime).

Instead, Plaintiffs feebly assert that *Employer Teamsters* is distinguishable because the plaintiffs' causes of action sounded in contract rather than tort. As an initial matter, Plaintiffs are wrong that a claim for breach of the implied warranty sounds in contract; as the West Virginia Supreme Court of Appeals recently affirmed, it is a "tort-based cause[] of action." *State ex rel.*

[1] All emphases added unless otherwise indicated.

3M Co. v. Hoke, 244 W. Va. 299, 852 S.E.2d 799, 803 (2020). In any event, Plaintiffs fail to cite any West Virginia law to support their suggestion that West Virginia law applies a different, more stringent test for proximate causation in contract cases than it does in tort cases. Rather, as the court recognized in *Employer Teamsters*, "the same guiding principles" apply in assessing proximate causation irrespective of the "various causes of action" asserted by the plaintiff. 969 F. Supp. 2d at 475.

Plaintiffs' attempt to distinguish *City of Charleston v. Joint Commission*, 473 F. Supp. 3d 596 (S.D. W. Va. 2020), is likewise unavailing. There, it is undisputed that the plaintiffs brought tort claims under West Virginia law based on substantially the same set of alleged injuries at issue here—harms to the City of Huntington and other municipal entities resulting from the opioid epidemic. Judge Copenhaver noted that "courts have applied the principles of remoteness to state law tort claims insofar as proximate cause requires 'carefully drawing a line so as to distinguish the direct consequences in a close causal chain from more attenuated effects influenced by too many intervening causes.'" *Id.* at 628 (quoting *Employer Teamsters*, 969 F. Supp. 2d at 472–73). Applying that law, the court granted the defendants' motion to dismiss, explaining that "defendants' actions are too attenuated and influenced by too many intervening causes, including the criminal actions of third parties, to stand as the proximate cause of plaintiffs' injuries." *Id.* at 631; *see also id.* ("no injury would occur unless the physician proceeded to unnecessarily prescribe opioid treatments or if patients obtained the drugs through some other illegal means").

Contrary to Plaintiffs' assertions, the court in *City of Charleston* neither held nor suggested that proximate causation exists as to the wholesale distributors in this case. Rather, the court merely stated a view that the defendant there—the Joint Commission healthcare accreditation organization—was *further* removed in the causal chain than wholesale distributors. *See* 473 F.

Supp. 3d at 630–31. Whether that is true or not,[2] the same independent actors whose intervening conduct defeated a showing of proximate causation in that case—*i.e.*, the doctors who wrote allegedly inappropriate prescriptions and the criminal actors who improperly diverted and abused prescription opioids—stand between Defendants and any of Plaintiffs' alleged harms and therefore also establish the absence of proximate causation here.

The facts of *City of Charleston* demonstrate why proximate causation cannot be established here. The allegation in *City of Charleston* was that the Joint Commission—which promulgated the concept of "Pain as the Fifth Vital Sign"—had caused the overprescribing of opioids and thereby created the opioid epidemic. 473 F. Supp. 3d at 606–07, 615–16. Yet those allegations, which were far more directly tied to prescribing behavior than anything done by Defendants, were insufficient to establish proximate causation. *Id.* at 630–31. And *City of Charleston* was decided on a motion to dismiss, without the full evidentiary record now before the Court that conclusively demonstrates the lack of proximate causation.

Finally, Plaintiffs are wrong to suggest that Defendants are not entitled to judgment even under a foreseeability standard. Defendants' conduct consisted of delivering FDA-approved prescription opioid medicines to State-licensed pharmacies. The evidence shows that (1) the increase in Defendants' shipments was overwhelmingly caused by increases in the number of prescriptions being written in good faith by West Virginia doctors and (2) Defendants had absolutely no ability to evaluate or second-guess those good-faith medical judgments. *See, e.g.*, Br. 16–23. Plaintiffs do not explain how the downstream harms they associate with increased opioid prescribing—such as when intravenous drug users contract HIV or endocarditis after

[2] The *City of Charleston* court made that statement without briefing or factual development on the role of wholesale distributors.

injecting heroin, *see* Opp. 26–28—could possibly have been foreseeable to wholesale distributors (who do not make medical judgments about patients) when it was not foreseeable to the doctors who were writing those prescriptions, to the FDA that was approving new medications, to the West Virginia Board of Medicine that was encouraging the use of prescription opioids, or to the DEA, which consistently increased the quotas for prescription opioids during the relevant time-period based on its belief that there was an increased legitimate medical need for the medicines. *See generally City of Charleston*, 473 F. Supp. 3d at 631 ("Nothing in the complaint indicates that defendants would reasonably foresee that … downplaying the risk of opioid treatments would result in these addiction-related crimes."). Plaintiffs certainly do not explain how these downstream harms were foreseeable to Defendants when Plaintiffs' own expert, Mr. Rafalski, admitted that he knew of no instance in which Defendants' customers dispended opioids other than to fill a legitimate prescription. *See* 5/26 Tr. (Rafalski) at 131:6–10.

Intervening/Superseding Causes. Plaintiffs argue that (1) an intervening act is a superseding cause only if the act was not foreseeable, and (2) the defendant bears the burden of proving superseding causation. But these arguments attack straw men because Defendants do not argue that the independent actions identified in their opening briefs are "superseding acts" that break off proximate causation. Rather, Defendants' alleged misconduct is too remote to constitute a proximate cause in the first place, as a matter of law.

For similar reasons, Plaintiffs' reliance on *Wal-Mart Stores East, L.P. v. Ankrom*, 244 W. Va. 437, 854 S.E.2d 257, 270 (W. Va. 2020), is misplaced. That case involved a direct chain of causation, in which the plaintiff was injured at the same time as and as a direct result of Wal-Mart employees' handling of a shoplifter (in violation of Wal-Mart policy). *See id.* (declining to overturn jury verdict in favor of plaintiff). The court noted that an "intervening act" does not

relieve a defendant of liability for its negligence unless it "operates independently of any other act," and held that a "reasonable juror" could have concluded the shoplifter's "decision to flee … did not operate independently of" the Wal-Mart employee's actions, such that the shoplifter's flight "was not the sole proximate cause of [the plaintiff's] injury." *Id.* at 270, 272. In short, the court found that the plaintiff was injured as a direct result of the actions Wal-Mart took.

Here, there can be no argument that doctors, pharmacists, illicit drug users, or criminal diverters did what they did because of any actions taken by Defendants. The evidence is that Defendants have no involvement in the prescribing decisions of doctors[3]—and there is no evidence that criminals divert drugs or illicit users take drugs because of Defendants' conduct. In addition, Defendants' argument is that Plaintiffs failed to prove that Defendants were a direct cause in the first place—not that, even if they were, the actions of doctors, drug dealers and others interrupt that causal chain. Accordingly, the *Wal-Mart* decision is simply irrelevant.

Finally, there is nothing new about the decision in *Wal-Mart*. Indeed, *City of Charleston* itself recognized the same rule that, under West Virginia law, a "tortfeasor whose negligence is a substantial factor in bringing about injuries is not relieved from liability by the intervening acts of third persons if those acts were reasonably foreseeable by the original tortfeasor at the time of his negligent conduct." 473 F. Supp. 3d at 627. But that did not stop Judge Copenhaver from holding that the defendant's alleged wrongdoing was "too attenuated … to stand as the proximate cause of plaintiffs' injuries." *Id.* at 631.[4]

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[3] *See infra* pp. 24–25.

[4] *Wehner v. Weinstein*, 191 W. Va. 149, 444 S.E.2d 27 (1994), is distinguishable for the same reasons. In that case, the defendant pizza delivery company admitted that its driver negligently parked a delivery truck in a manner that blocked a fraternity driveway, but argued that the conduct of the fraternity brothers who attempted to move the car were "intervening causes" of injuries that resulted when the car rolled down a hill. *See id.* at 32–33. The delivery company did not argue

Multiple Causes. Plaintiffs again attack a straw man when they assert that an actionable injury may have "more than one cause." Opp. 4, 31. Defendants do not dispute this. Rather, Defendants are entitled to judgment because Plaintiffs have failed to come forward with evidence that any Defendant was ***a*** proximate cause of the injuries underlying Plaintiffs' claims.

Lessened Causation Standard. Plaintiffs' assertion that the "burden of proving causation is less strict for a public nuisance claim" is unsupported. Opp. 5. The only West Virginia authority they cite is a trial-court decision in a state opioid case in which the court requested that the parties submit proposed findings of fact and conclusions of law and then adopted the plaintiffs' submission ***verbatim***. *Id*. (quoting *Brooke Cty. Comm'n v. Purdue Pharma L.P.*, No. 17-C- 248 (W. Va. Cir. Ct. Dec. 28, 2018)). Thus, Plaintiffs are simply citing their own say-so back to the Court. And the only authority on which the *Brooke County* decision relied was a 2003 decision by Judge Weinstein that (1) purported to apply New York law and (2) did not cite ***any*** authority for the bald assertion that "the cause need not be so proximate" in public nuisance cases. *See NAACP v. AcuSport, Inc.*, 271 F. Supp. 2d 435, 497 (E.D.N.Y. 2003).

In addition to having no sound basis in West Virginia law, Plaintiffs' proposed rule makes no sense. Proximate causation is a foundational principle underlying all of tort law, and there is no principled basis to apply a wholly different standard in public nuisance cases than any other case sounding in tort. The Court should therefore reject Plaintiffs' invitation to impose liability on Defendants based on a watered-down proximate causation standard with no basis in West Virginia law.

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remoteness, and the court rejected its argument that the third parties' conduct was independent, concluding that the fraternity brothers only tried to move the car *because* the pizza delivery driver blocked the driveway. *See id.* at 33.

Duty To Block Shipments. Finally, Plaintiffs assert that Defendants have a "legal duty not to ship orders they have or should have identified as suspicious unless the order is cleared." Opp. 43. The Court need not resolve that question to decide the case on proximate causation grounds because, even if Defendants have such a duty and breached it, there is no evidence that such a breach directly caused any of Plaintiffs' alleged injuries. Defendants therefore will not offer a detailed response to that assertion here. Defendants note, however, that the Court previously rejected Plaintiffs' request for summary judgment on that very question. *See* Order Denying Plaintiffs' Mot. for Partial Summary Judgment Concerning Defs.' Statutory and Regulatory Duties (ECF No. 1291). Moreover, for the reasons explained in Defendants' opposition to that motion, the governing regulations relied on by Plaintiffs do not impose any such duty. *See* Defs.' Mem. of Law in Opp. to Pls.' Mot. for Partial Summary Judgment Concerning Defs.' Statutory and Regulatory Duties (ECF No. 1079). And, as the trial record makes clear, each Defendant promptly put in place new systems that ***blocked and did not ship suspicious orders*** no later than 2008[5]—promptly after DEA first issued sub-regulatory guidance announcing its revised expectations regarding the shipment of "suspicious orders." *See United States v. $463,497.72*, 853 F. Supp. 2d 675, 682 (E.D. Mich. 2012) (identifying September 11, 2007 as the date on which DEA "told distributors" about its "new interpretation of the suspicious order regulation); *see also Masters Pharm., Inc. v. DEA*, 861 F.3d 206, 222 (D.C. Cir. 2017) (identifying the July 2007

[5] *See, e.g.*, 5/26 Tr. at 74:16–75:23, 207:2–6, 250:23–251:3 (Mr. Rafalski testifying that since the 2007-2008 timeframe, each Defendant operated a suspicious order monitoring system that blocked and did not ship orders determined to be "suspicious"); 6/9 Tr. at 13:18–24 (Mr. Rannazzisi testifying that by 2008, every Defendant had in place a policy that involved blocking suspicious orders); 5/25 Tr. (Oriente) at 9:2–12, 55:12–17 (McKesson's CSMP, which came into use in early 2008, blocked all orders that exceeded thresholds); 5/20 Tr. (Moné) at 189:12–19 ("Q: And when a pharmacist made a determination that an order was suspicious, what did Cardinal Health do next? A: The order was reported to DEA. Q: Was it shipped? A: No. Q: To your knowledge, during your time at Cardinal Health, did the company ever ship a suspicious order? A: No, it did not.").

Southwood administrative decision as the place where DEA "first articulated" its revised guidance).

***Direct Sales*.** Plaintiffs' continued reliance on *Direct Sales Co. v. United States*, 319 U.S. 703, 707 (1943) is likewise misplaced. See Opp. 51. That case does not—as Plaintiffs have suggested—hold (or even suggest) that the shipment of orders meeting the regulatory definition of "suspicious" is unlawful. Rather, it holds only that, if a seller of opiates "work[s] in prolonged cooperation with a physician's unlawful purpose to supply him with his stock in trade for his illicit enterprise, there is no legal obstacle to finding that the supplier not only knows and acquiesces, but joins both mind and hand with him to make its accomplishment possible." *Id.* at 713. In other words, *Direct Sales* stands—at most—for the proposition that a distributor may be liable as a co-conspirator if it knowingly and continuously facilitates its customer's illicit enterprise. *But cf. id.* at 712 & n.8 ("Concededly, not every instance of sale of restricted goods, harmful as are opiates, in which the seller knows the buyer intends to use them unlawfully, will support a charge of conspiracy."). Here, there is absolutely no evidence that any Defendant ever intentionally facilitated a customer's illegal operations or shipped even a single opioid pill that it believed was likely to be diverted.[6] Accordingly, *Direct Sales* is simply irrelevant here.

[6] To the contrary, the evidence showed that all Defendants at all times had in place systems that would prevent the shipment of orders that the Defendant determined were likely to be diverted to illicit use. *See, e.g.*, 5/12 Tr. at 203:11–17 (ABDC's Senior Vice President of Corporate Security and Regulatory Affairs, Chris Zimmerman, testified that if ABDC knew a pharmacy was diverting drugs "we wouldn't be selling [opioids] to them"); 5/20 Tr. at 230:10–14 (Cardinal Health's Vice President of Anti-Diversion, Michael Mone, testified that the company never shipped an order it believed would be used for other than legitimate medical purposes); 5/25 Tr. at 48:4–14, 55:12–20, 126:4–8 (McKesson's Director of Regulatory Affairs, Michael Oriente, confirming that at all relevant times McKesson blocked orders that it identified as likely to be diverted). Mr. Rafalski, after watching the testimony of these witnesses, did not dispute this fact.

II. PLAINTIFFS ARE WRONG ABOUT THE FACTS.

Given Plaintiffs' inability to establish that Defendants' alleged conduct was a direct cause of their alleged injuries, the Court need go no further. Under *City of Charleston* and *Employer Teamsters*, and as explained above and in Defendants' opening brief, Plaintiffs' claims should be rejected based on the undisputed record evidence establishing that their claims are unduly remote. In addition, the Opposition makes clear that Plaintiffs' claims are also foreclosed on the facts. In particular, several critical concessions in the Opposition underscore Plaintiffs' failure to carry their evidentiary burden in this case under any conception of proximate cause.

First, Plaintiffs acknowledge—as they must—that the standard of care for the treatment of pain changed beginning in the 1990s, and that this change in the standard of care resulted in a significant increase in the volume of opioid medicines prescribed in good faith by doctors in West Virginia and elsewhere. *See, e.g.*, Opp. 2. The volume of prescription opioids shipped by Defendants was determined by those good faith prescriptions, and Plaintiffs have no evidence that Defendants were a direct and independent cause of any "oversupply" in Cabell/Huntington.

Second, Plaintiffs tacitly admit that medicine cabinet diversion played a substantial role in fueling Cabell/Huntington's opioid epidemic, and that Defendants have no ability to prevent medicine cabinet diversion. Accordingly, in order to prove a direct connection between Defendants' conduct and any diversion in Cabell/Huntington, Plaintiffs needed to prove that (1) Defendants improperly shipped some additional increment of pills—over and above the volume that was needed to meet the demand created by that good-faith prescribing—that they knew or should have known were likely to be diverted, and (2) those pills were in fact diverted and then caused the alleged downstream harms that underlie Plaintiffs' claims. No record evidence supports either proposition.

Third, none of the evidence cited in the Opposition establishes proximate causation. Although Plaintiffs purport to identify a number of "outlier" prescribers and pharmacies, it is a mathematical certainty that some prescribers and pharmacies will fall above the average, and Plaintiffs do nothing to prove any wrongdoing on the part of those persons or entities—let alone Defendants. Moreover, although Mr. Rafalski purports to identify an implausibly large number of orders that Defendants should have blocked and not shipped, he did not actually review any of those orders and does not know whether they were actually suspicious, diverted, or caused any harm. Accordingly, the Court should afford no weight to Mr. Rafalski's incredible and unreliable *ipse dixit* analysis. Finally, although Dr. Keyes purports to draw a connection between the quantity of opioids in a community and opioid-related harm, she has no opinion that Defendants actually ***caused*** (let alone proximately caused) the oversupply.

A. No Evidence that Defendants Proximately Caused Oversupply.

Defendants' brief explained how the volume of prescription opioids in Cabell/Huntington was ***not*** determined by Defendants, but rather by doctors' good faith prescribing decisions in accordance with then-prevailing standard of care. *See* Br. 14–23. Plaintiffs do not meaningfully dispute that (1) the standard of care changed, (2) doctors were writing more prescriptions, (3) Defendants had no ability to second-guess those prescribing decisions, or (4) Defendants' shipment volumes were determined by the prescription volume. Those points conclusively demonstrate the absence of a direct relationship between Defendants' conduct and the alleged "oversupply" of prescription opioids, and thus are dispositive here.

Plaintiffs' entire argument boils down to the facile assertion that the shipment of approximately "80 million dosage units" of prescription opioids into Cabell/Huntington over a 22-

year period is—in and of itself—proof of wrongdoing by Defendants.[7] Plaintiffs say that "[t]ens of millions of the opioid pills Defendants shipped to and near Cabell and Huntington could not have been prescribed in accordance with the standard of care, and instead could only have been intended for illicit, non-medical use." Opp. 32. But they do not cite any record evidence for that assertion—because there is none.

Not a single witness testified that the volume of prescription opioids shipped into a given community or to a given pharmacy, standing alone, can establish wrongdoing on behalf of a distributor. And ample record evidence contradicts that assertion, including that:

- The vast majority of doctors—over 99%—were prescribing in good faith, *see* Br. 5, 20–21;
- According to Plaintiffs' own expert, Dr. Keyes, inappropriate prescribing by "[p]ill mills do not explain in any significant way the expansion of opioid prescribing and opioid-related harm," 6/14 Tr. at 131:11–22;
- The number of opioids dispensed in Cabell/Huntington matches almost perfectly the number prescribed to patients by doctors, *see* 5/15 Tr. at 213:8–214:23 (Ms. Keller testifying that average opioid pills prescribed in Cabell County was 141.2 pills per person while opioid pills distributed was 142.19 pills per person);
- As Plaintiffs concede, the standard of care changed over the relevant time-period, resulting in a significant increase in the total amount of opioid prescriptions written by doctors nationwide, *see supra* p. 11;
- DEA itself recognized that there was a growing legitimate medical need for opioid medicines, continuously increasing the aggregate production quotas for prescription opioids from the late 1990s through the 2010s;[8]

[7] Plaintiffs' aggregate distribution figure is based on different time periods of distribution for each Defendant: AmerisourceBergen's distribution is measured from 2002–2018, Cardinal's distribution is measured from 1996–2018, and McKesson's distribution is measured from 2004–2018. *See* 5/10 Tr. (McCann) at 87:23–91:8.

[8] In September 2019, the DOJ's Office of the Inspector General published a report concluding that "from 2003 to 2013, DEA authorized manufacturers to produce substantial amounts of opioids. For example, the [quota] of oxycodone . . . increased over 400 percent" during that timeframe. *See* Trial Ex. DEF-WV-01597 at 13; *see also id.* at Figure 3. Mr. Rafalski did not dispute these

- Communities such as West Virginia generally and Cabell/Huntington in particular—because they have a disproportionate share of older, sicker residents and residents with physically demanding jobs—use a greater percentage of all medicines, including prescription opioids, *see, e.g.*, Br. 17 n.27; and

- DEA never advised Defendants that their distribution volume was too high, *see* 6/9 Tr. (Rannazzisi) at 92:18–21, and there is no evidence that Plaintiffs or any other government entity did so either.

In short, the record evidence conclusively undercuts Plaintiffs' assertion—made without citation to any record evidence—that (1) the volume of Defendants' shipments is itself evidence of wrongdoing or (2) any meaningful portion of Defendants' shipments into Cabell/Huntington were dispensed other than pursuant to a legitimate prescription written in good faith by a doctor.

Consistent with the allegations in their complaint regarding purportedly fraudulent manufacturer marketing, *see* Third Amend. Compl. ¶¶ 372–76, 379–511, 538–650, Plaintiffs also assert that manufacturer's "promotional conduct [helped] to change the standard of care towards increased opioid prescribing," Opp. 44. But their feeble efforts to tie Defendants to that conduct fall flat.

Plaintiffs' only marketing witness was Dr. Jakki Mohr. While Dr. Mohr testified to the unsurprising and uncontroversial proposition that Defendants, like most companies in the United States, engaged in "marketing," she further testified that:

- she had no opinion that anything in any marketing communication by a distributor was false or misleading, 6/8 Tr. at 97:3-5, 123:22-124:2;

- she had no opinion that any of the marketing activities by a distributor was unlawful, 6/18 Tr. at 124:3-6;

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findings. *See* 5/26 Tr. (Rafalski) at 181:14–182:1. Mr. Rannazzisi—who was responsible for overseeing DEA's quota unit and signing off on the annual quotas—admitted that the quotas for oxycodone and hydrocodone began rising in the late 1990s and continued to increase significantly during his tenure, and he defended those raises in the quota as necessary to meet patient needs in the United States. *See* 6/8 Tr. (Rannazzisi) at 198:8–18, 199:2–4; 6/9 Tr. (Rannazzisi) at 187:20–188:9.

- Defendants' marketing activities were not improper, 6/18 Tr. at 112:19-21, 124:7-10;
- Defendants' marketing activities were typical of those seen across a range of industries, 6/18 Tr. at 112:22-113:3, 127:3-23; and
- she did not attempt to evaluate the effect of distributors' marketing practices on sales of prescription opioids, 6/18 Tr. at 97:6-13.

No other Plaintiff witness testified that Defendants' so-called marketing was false, misleading, or otherwise improper. Accordingly, the Court should reject Plaintiffs' unsupported attempt to impute liability to Defendants by suggesting—but by no means proving—that Defendants participated in manufacturers' allegedly misleading marketing campaign.

B. No Evidence that Defendants Proximately Caused Diversion.

The evidence cited in Plaintiffs' opposition cannot save their claims for a second and independent reason: none of it establishes that diversion occurred at any of Defendants' pharmacy customers in Cabell/Huntington. Plaintiffs' theory of liability is that Defendants had a duty to prevent diversion. Accordingly, Plaintiffs needed to show (at a minimum) that (1) a Defendant made shipments into Cabell/Huntington that the Defendant should not have made, (2) those shipments actually led to diversion occurring in Cabell/Huntington, and (3) that diversion was a substantial factor in causing the harms underlying Plaintiffs' claims. Because Plaintiffs have not done that, Defendants are entitled to judgment on these facts.

The record evidence establishes only two categories of diversion in Cabell/Huntington. *First*, the record shows (and Plaintiffs concede) that diversion occurred when leftover pills were diverted from a patient's medicine cabinet—for instance, when they were taken by family members or given away by patients. *See* Pls.' Consolidated Response to Defs.' Mots. for Judgment Re: Abatement (ECF 1470) at 6 ("as the volume of drugs increase, so too does the risk that drugs

will be kept in patients' homes, where they may be diverted").[9] While this form of diversion was common, the record further establishes that Defendants had no duty to prevent medicine cabinet diversion and are not a proximate cause of any harm flowing from it. *See, e.g.*, 5/26 Tr. at 196:7–11 (Mr. Rafalski agreeing that when a prescription is legitimately written and dispensed, it is patients—and not distributors—who control what happens to it thereafter); 6/9 Tr. at 154:14–20, 155:3–7 (Mr. Rannazzisi testifying that it is not the role of distributors to "evaluate a patient's legitimate medical need for opioids" and that distributors are not required to "Know [Their] Customer's Customer"—*i.e.*, the patients who obtain prescription medicines from pharmacies); *City of Charleston*, 473 F. Supp. 3d at 631 (concluding that the "criminal actions of third parties, such as 'illegal drug trafficking,'" rendered the plaintiffs' claims too remote as a matter of law).

Second, the record shows that diversion occurred at one particular pharmacy in Cabell/Huntington—A-Plus Care Pharmacy in Barboursville—which was "a major source of supply for pharmaceutical diversion to the tri-state area and beyond" and was shut down by local law enforcement in 2014.[10] The record, however, further shows that ***no Defendant ever supplied***

[9] *See also, e.g.*, 5/4 Tr. at 174:23–175:5 (Dr. Waller describing how diversion of unused opioid pills occurs between friends and family members); 5/6 Tr. (Gupta) at 91:14–25 (agreeing that excess pills prescribed by doctors for an underlying legitimate need may end up in the medicine cabinets or drawers of people's homes and then out in the community); 5/26 Tr. at 199:11–18 (Mr. Rafalski taking no issue with statistics showing that "more than three out of four people who misuse prescription painkillers use drugs prescribed to someone else"); 6/9 Tr. (Rannazzisi) at 141:3–10 (confirming that the government's position was that the most frequent method of obtaining a controlled substance for non-medical use was through friends and family); 6/14 Tr. (Keyes) at 71:19–72:7 ("Pervasive over-prescribing resulted in unused prescribed opioid medications diverted for monetary value, bartered, or for no cost among family and individuals in a shared social network."); Trial Ex. MC-WV-02079 (Compton 2019) at 6 (stating that more than half of people who misuse prescription opioids report obtaining them from friends or family members who have prescriptions and concluding that as a result of overprescribing, "unused pills became increasingly available for diversion and misuse").

[10] *See* Trial Ex. P-41220 (HPD 2014 Annual Report) at 20. According to the Huntington Police Department's Annual Report, A-Plus Care Pharmacy was responsible for *97%* of the diverted prescription opioid pills seized in 2014. *Id.*; *see also* 5/21 Tr. (Lemley) at 256:6-10.

the A-Plus Care Pharmacy. *See, e.g.*, 5/26 Tr. (Rafalski) at 152:2–22 (acknowledging that Miami-Luken was the only supplier of the A-Plus Care Pharmacy); 5/12 Tr. (McCann) at 27:6–13.

Other than the A-Plus Care Pharmacy, there is ***no record evidence of any diversion occurring at the pharmacy level*** in Cabell/Huntington. For example, Mr. Rafalski disavowed any knowledge of pharmacy-level diversion in Cabell/Huntington:

> Q…. You're not offering any opinions about whether diversion occurred at a pharmacy level; correct?
>
> A. I haven't put that opinion in my report, so I guess that's a true statement, Your Honor.

5/26 Tr. at 135:10–13. Because Plaintiffs have not come forward with any competent evidence of diversion occurring at any of Defendants' pharmacy customers in Cabell/Huntington, they have not shown that Defendants' alleged wrongdoing was a cause (let alone a proximate cause) of their alleged injuries.

Plaintiffs' principal response is an assertion that they have evidence suggesting that Defendants' purported "failure to maintain effective controls against diversion in fact resulted in the occurrence of diversion." Opp. 6. But the evidence that Plaintiffs go on to cite actually does no such thing. Instead, the cited evidence establishes only the uncontested proposition that a failure to maintain effective controls ***can potentially*** result in diversion. At the close of Plaintiffs' evidence, that is simply not enough.

Plaintiffs, for example, cite Dr. David Courtwright for the proposition the purpose of "the 'closed system' of distribution" created by the CSA was (in part) "to prevent diversion." Opp. 6. Similarly, they cite the testimony of various DEA officials, such as the designated deposition testimony of Matthew Strait, that "increases in availability could have the unintended consequence of increasing diversion and abuse." Opp. 7. And they cite the testimony of Defendants' employees, such as the designated deposition testimony of Nathan Hartle, who acknowledged that

regulatory compliance is "'extremely important' in order to 'prevent the diversion of controlled substances.'" Opp. 9. Tellingly, however, ***none of the witnesses actually testified that any of Defendants' pharmacy customers in Cabell/Huntington were engaging in diversion***—let alone that the Defendant who supplied that pharmacy knew or should have known about it. Indeed, most (if not all) of Plaintiffs' witnesses were admittedly not competent to testify on this topic. Mr. Rannazzisi, for instance, made clear that he "ha[d] not reviewed any documents related to West Virginia" and therefore could not identify "any orders in Huntington or Cabell County that [he] believed … should have been blocked by one of the defendants but were not." 6/9 Tr. (Rannazzisi) at 14:6–17. And Mr. Rafalski, as previously noted, disclaimed any knowledge or opinion of whether diversion was occurring at the pharmacy level in Cabell/Huntington. 5/26 Tr. at 135:10–13.

Plaintiffs also cite the testimony of Cabell/Huntington law enforcement officials—who, presumably, would have been in a position to say so if there were evidence of diversion occurring at any of Defendants' pharmacy customers in Cabell/Huntington. For example, Plaintiffs cite Huntington's Former Chief of Police, William Holbrook, for the proposition that law enforcement "would see some evidence where it looked like maybe a ***pharmacist*** or a ***doctor*** potentially was, again, distributing, prescribing drugs, opioids irresponsibly." Opp. 9. But this testimony is entirely disconnected from any Defendant or any Defendants' pharmacy customer—and thus entirely irrelevant to the issues currently before the Court. For example, the record establishes at least one instance where a pharmacy (A-Plus) was dispensing illegally, but that pharmacy was not serviced by Defendants. *See supra* p. 17.

Finally, Plaintiffs cite the *ipse dixit* opinion of Mr. Rafalski that the roughly 40% of orders flagged by his Method B were "more likely than not" diverted. Opp. 8-9. As an initial matter,

that opinion should be excluded for the reasons explained by Defendants in their renewed *Daubert* motion (ECF No. 1386). Moreover, even if admitted, the opinion is not credible and should be afforded no weight.

As an initial matter, Plaintiffs themselves have elsewhere made clear that "***Mr. Rafalski is not expressing an opinion on the number of suspicious orders that were actually diverted***." Pls.' Response to Mem. in Support of Cardinal Health's Motion for Judgment Re: Unreasonable Interference With a Public Right (ECF No. 1472) at 34. That admission alone should end the matter. Moreover, Mr. Rafalski himself admitted a number of facts that directly contradict his *ipse dixit* opinion that all of his "flagged" orders were likely to be diverted. For example, Mr. Rafalski admitted that he did not:

- know "how many" of the "suspicious orders that have occurred over time" were "actually diverted," 5/26 Tr. at 205:18–22;
- "actually review any of the orders" that he concluded "were likely to be diverted" before rendering his opinions, 5/26 Tr. at 214:13–15, 215:1–7;
- identify "a single doctor … in Cabell County or Huntington who was prescribing improperly or engaging in diversion," 5/26 Tr. at 128:11–15;
- know "of any pills that were shipped by [Defendants] that ended up filling a prescription that was dispensed other than in response to a licensed prescriber writing a prescription," 5/26 Tr. at 131:6–10.
- know what percentage of the orders he identified as likely to be diverted "were actually investigated and … cleared" by Defendants, 5/26 Tr. at 228:21–229:6; or
- consider that, when DEA was tasked by Congress to estimate "how much diversion is occurring," it estimated "less than .1 percent diversion" for oxycodone and hydrocodone, and did not undertake "the type of calculation of actual diversion that the DEA has conducted," 5/26 Tr. at 249:11–250:13.

Furthermore, as discussed more fully below, Mr. Rafalski admitted that good-faith prescribing was increasing substantially during the period covered by his analysis, and yet he made no effort to account for that in developing his flagging methodologies. *See infra* p. 29–30. In

other words, Mr. Rafalski did not even check to see whether the increased number of orders flagged by his analysis (based on a cap fixed for all time after six months) were actually problematic, as opposed legitimate responses to increases in the level of good-faith prescribing. Accordingly, Mr. Rafalski's unfounded opinion that all such flagged orders were likely to be diverted is simply not reliable or credible.

In short, there is no competent evidence that any Defendant ever supplied a pharmacy in Cabell/Huntington that was engaged in diversion—let alone competent evidence that a Defendant ever supplied a pharmacy in Cabell/Huntington that the Defendant knew or should have known was engaged in diversion. Without any such evidence, Plaintiffs' claims fail as a factual matter and Defendants are entitled to judgment.

C. The Evidence Cited By Plaintiffs Does Not Establish Proximate Causation.

Lacking any evidence proving that Defendants proximately caused either (1) the purported "oversupply" of prescription opioids or (2) any diversion in Cabell Huntington, Plaintiffs instead point principally to expert testimony from Ms. Keller, Mr. Rafalski, and Dr. Keyes. But those witnesses either (1) said nothing relevant on proximate causation ***as to Defendants*** or (2) were entirely incredible and unreliable. Accordingly, the cited evidence does not satisfy Plaintiffs' burden of proving proximate causation.

1. Plaintiffs' "Outlier" Evidence Is Irrelevant.

The Opposition purports to identify a number of "outlier" pharmacies and prescribers that are somehow connected to Defendants. That evidence is irrelevant to the questions presented in Defendants' motion.

"Outlier Pharmacies." Plaintiffs' efforts to identify "outlier" pharmacies in Cabell/Huntington cannot rescue their claims. For a handful of pharmacies, Plaintiffs compare a given Defendant's shipments with the same Defendant's national and state-wide distribution

averages. *See* Opp. 36–42. For example, Plaintiffs state that "ABDC's shipments of oxycodone to the McCloud Family Pharmacy … is over 3.5 times ABDC's national average [and] double its West Virginia average." Opp. 37. Based solely on those comparisons, the Opposition goes on to state—again without any record citation[11]—that those distributions "cannot be explained solely or 'overwhelmingly' by the prescribing standard of care." Opp. 36–41.

But saying it does not make it so, and Plaintiffs' cherry-picked comparisons to national and state-wide averages prove absolutely nothing—other than the mathematical certainty that, whenever a large number of measurements are averaged, a significant portion of the individual data points will be above average. That truism does not establish that those pharmacies were ordering improperly or engaged in diversion, or that Distributors acted improperly by filling any of their orders. To the contrary, Plaintiffs' own witnesses explained that there can be perfectly legitimate reasons that certain pharmacies order greater numbers of prescription opioid medicines. *See, e.g.*, 5/26 Tr. at 204:12–16, 205:8–11 (Mr. Rafalski agreeing that there are all kinds of circumstances where an order can be of unusual size, pattern or frequency, but not be diverted); 6/9 Tr. at 81:11–13 (Mr. Rannazzisi testifying that over-threshold orders are not necessarily suspicious, because the ordering pharmacy may be next to a cancer center, palliative care center, or hospital).

"Outlier" Prescribers." Plaintiffs devote a substantial portion of their opposition to a discussion of so-called "outlier prescribers." Opp. 32-36. This evidence does not help Plaintiffs for the same fundamental reason described above—*i.e.*, evidence regarding deviations from averages is not itself indicative of wrongdoing—as well as the additional reasons explained below.

[11] Notably, no Plaintiffs witness—including Messrs. Rafalski and Rannazzisi—endorsed Plaintiff's apparent view that impropriety can be demonstrated by comparing a distributor's shipments to a particular pharmacy with that same distributor's statewide and nationwide averages.

First, the only Plaintiff expert to offer testimony regarding "outlier" prescribers—Lacey Keller—made clear just how limited her testimony actually was. While Ms. Keller used prescribing data that Plaintiffs purchased from a third party vendor to identify "top 1%" or "outlier" prescribers, she further testified that:

- she had no opinion that Defendants ***should*** have purchased and used the prescribing data that she relied on in her analysis, 6/15 Tr. at 159:13–160:9;
- she had no opinion on whether prescriptions written by top 1% prescribers were medically unnecessary or medically improper, 6/15 Tr. at 165:16-22;
- she had no opinion that any prescription written by a top 1% prescriber should not have been filled by a pharmacist or pharmacy, 6/15 Tr. at 166:21-167:13;
- she had no opinion that any of the top 1% prescribers were prescribing too many opioids, 6/15 Tr. at 169:9-15;
- she had no opinion about what Defendants should have done with knowledge that their customers were filling prescriptions from top 1% prescribers, 6/15 Tr. at 191:3-15;
- she had no opinion that a distributor should take any action against a pharmacy customer that fills prescriptions written a top 1% prescriber, 6/15 Tr. at 251:6-13; and
- many of the top 1% prescribers she identified have no disciplinary record and are still licensed by the Board of Medicine, 6/15 Tr. at 174:20-175:1.

In short, the testimony of Ms. Keller herself does nothing to establish that—even if Defendants had performed an analysis similar to hers—that they could or should have done anything different as a result of that analysis.

Plaintiffs' other witnesses do not fill any of these evidentiary gaps. To the contrary, they explain ***why*** Ms. Keller's analysis of "outlier" prescribers is irrelevant. *First*, Mr. Rannazzisi made clear that volume alone cannot be used to determine whether a doctor is prescribing inappropriately:

> Q. Did you ever have a criteria that if a doctor fell within the top one percent, they would automatically be investigated in terms of their prescribing levels?

A…. [***W***]***e don't investigate based on quantities***.

6/9 Tr. at 112:16–113:5; *see id.* at 99:10–16 (DEA never told a Defendant that "they should stop supplying to a pharmacy in Huntington or Cabell because of a DEA registered doctor whose prescriptions were being filled at that pharmacy"); *see also* 5/6 Tr. (Gupta) at 143:11–15 (testifying that the West Virginia Board of Medicine would not initiate an investigation of a prescriber simply because they were prescribing a high volume of opioids). This is because, as Mr. Rannazzisi acknowledged, there is nothing inherently suspicious about being a high-prescriber. *See* 6/9 Tr. (Rannazzisi) at 197:15–21 (agreeing that "[j]ust because a physician is a pain specialist, that doesn't mean that they're prescribing in any sort of a rogue fashion"); *see also* T. Prevoznik 4/18/19 Dep. Designations at 492:4–6, 492:9–16, 492:20 (DEA agreeing that not all pain clinics diverted controlled substances).

Second, and more fundamentally, Plaintiffs' witnesses were unanimous in testifying that ***it is not Defendants' role to police or second-guess the prescribing decisions of doctors***. For example, Mr. Rannazzisi testified that wholesale distributors:

- do not evaluate a patient's legitimate medical need for opioids in terms of deciding whether the opioids are appropriate for that patient, 6/9 Tr. at 154:17–155:2;
- cannot second-guess legitimate medical decisions by prescribers, 6/9 Tr. at 154:17–155:2;
- do not have access to the information needed to evaluate the medical need of an individual patient," 6/9 Tr. at 149:3–13; and
- cannot make the determination if a controlled substance is medically necessary for a particular patient, 6/9 Tr. at 98:16–19.

In addition, Mr. Rafalski testified that it is the responsibility of doctors—and not distributors—to make judgments about whether opioid medicines are an appropriate treatment. *See* 5/26 Tr. at 116:15-117:22, 148:25–149:13. The testimony of Plaintiffs' other witnesses is the same. For example:

- Dr. Waller testified that the decision whether to prescribe opioid medicines and what dosage to prescribe is made by doctors in collaboration with their patients, *See* 5/4 Tr. at 88:13–89:4. Dr. Waller further testified that distributors do not play a role in decision-making process for opioid prescribing and do not directly interact with patients. *See id.* at 87:21–89:4, 90:19–21.

- Dr. Gupta testified that the decision on using opioids for chronic pain treatment should be entrusted to the decision of a licensed doctor acting in concert with the patient. *See* 5/5 Tr. at 188:24–189:1; 5/6 Tr. at 46:10–15, 68:7–11, 68:25–69:8, 76:20–77:10.

- Dr. Werthammer agreed that wholesale distributors do not prescribe medicines. *See* 5/21 Tr. at 22:14–16.

- Dr. Yingling testified that distributors do not interact with doctors related to the care and treatment of individual patients, and have never influenced his own prescribing practices. *See* 6/16 Tr. at 188:2–8.

- Dr. Smith testified that a prescribing physician is in the best position to evaluate the risks and benefits, including the risk of addiction, of prescribing any specific drug to a patient. *See* 6/10 Tr. at 162:12–20. Dr. Smith further testified that distributors have no involvement with individual patients and could not evaluate individual risks of addiction. *See id*. at 162:21-163:2.

- Mayor Williams testified that it is up to a physician to decide who has a legitimate need for prescription opioids. *See* 6/30 Tr. at 81:25–82:4.

In short, the overwhelming weight of the record evidence establishes that (1) a high-prescribing doctor is not necessarily prescribing inappropriately, (2) none of Defendants' customers ever filled a prescription written by anyone other than a State-licensed, DEA-registered doctor, and (3) wholesale distributors have neither the ability nor any duty to second-guess the prescribing decisions of doctors. Accordingly, Plaintiffs' "outlier prescriber" evidence does not provide a basis upon which to impose liability on Defendants.

2. Plaintiffs' Out-of-Jurisdiction Evidence Is Irrelevant.

Even further afield are Plaintiffs' strained efforts to identify allegedly problematic pharmacies serviced by Defendants outside of Cabell/Huntington. As a legal matter, these are not the right Plaintiffs to recover for alleged wrongdoing that occurred outside of Cabell/Huntington.

And, as a factual matter, Plaintiffs have failed to demonstrate any nexus between Defendants' alleged extraterritorial misconduct and the harms underlying Plaintiffs' claims.

Plaintiffs devote a substantial portion of their opposition to describing the volume of Defendants' shipments to "outlier pharmacies" that are located ***outside*** of Cabell/Huntington. Specifically, they identify 13 pharmacies located in 8 different counties that are located as far as 165 miles from Cabell Huntington.[12] At the outset, this evidence is insufficient for the reasons explained above—*i.e.*, that bare comparisons of distribution volumes for a given pharmacy to statewide and national averages proves nothing. In addition, this evidence is irrelevant because Plaintiffs have failed to introduce evidence that Defendants' distributions to these pharmacies led to diversion or harm in Cabell/Huntington.

As this Court has recognized, evidence of Defendants' distributions to specific pharmacies outside Cabell/Huntington is not relevant unless Plaintiffs establish a "demonstrable nexus" between those distributions and any diversion in Cabell/Huntington. *See* ECF No. 1297 at 10. No such evidence exists in the record. To be sure, Plaintiffs point to generalized evidence suggesting that diversion can occur "across state, county, and municipal boundaries." Opp. 11. But that is not the relevant question. Rather, even assuming *arguendo* that these Plaintiffs may recover based on conduct occurring outside Cabell/Huntington at all, the question is whether they have come forward with any evidence establishing that diversion occurring at one of the extra-territorial pharmacies identified in their opposition in fact did contribute in any meaningful way to the harms underlying their claims. Because they have not, the evidence on which they rely is irrelevant.

[12] Fritz's Pharmacy and Wellness, located in Greenbrier County, is about 165 miles from the City of Huntington.

Even less relevant is the evidence (more than a decade old) regarding Internet pharmacies located principally in Florida. Here again, there is no concrete evidence tying Defendants' conduct in Florida (or elsewhere) to any harms in Cabell/Huntington. Moreover, as the very testimony cited by Plaintiffs makes clear, Defendants' extraterritorial shipments could not be a proximate cause of any injuries that might have occurred to Cabell/Huntington residents. And since Internet pharmacies were banned in 2008, *see* 6/8 Tr. (Rannazzisi) at 215:12–20, this evidence is entirely stale in a forward-looking nuisance case.

For example, Plaintiffs cite the testimony of Mr. Rannazzisi about unidentified "people that go down to Florida to visit pill mills" and "take the drugs back to where they came from." Opp. 10. Similarly, they cite the testimony of Appalachia High Intensity Drug Trafficking Area Director Vic Brown, who discussed "citizens traveling out of state to obtain prescription medication." Opp. 11. But none of this generic testimony establishes that (1) a Defendant made wrongful shipments to a particular pharmacy in Florida or elsewhere and (2) those shipments actually led to any injury occurring in Cabell/Huntington. Moreover, the testimony makes clear that the intervening, illegal conduct of either a drug dealer who imported prescription pills into Cabell/Huntington for re-sale or a Cabell/Huntington resident who traveled to Florida in order to obtain pills for illicit use was the immediate and independent cause of any injury.

In short, Defendants' distributions of FDA-approved medicines to DEA-registered pharmacies in Florida could not have led to any injury in Cabell/Huntington but for the independent, illegal conduct of third party drug dealers and drug users, and so could not have been a proximate cause of Plaintiffs' alleged injuries. *See, e.g.*, *City of Charleston*, 473 F. Supp. 3d at 631 (concluding that the "criminal actions of third parties, such as 'illegal drug trafficking,'" rendered the plaintiffs' claims too remote as a matter of law).

3. Mr. Rafalski's Flagging Testimony Is Irrelevant and Not Credible.

Based ***solely*** on the testimony of Mr. Rafalski, Plaintiffs assert that Defendants collectively shipped approximately 30 million "dosage units of oxycodone and hydrocodone into Cabell and Huntington that should have been flagged and blocked." Opp. 6. For the reasons explained in Defendants' renewed *Daubert* motion on Mr. Rafalski, ECF No. 1386, Mr. Rafalski's testimony should be excluded. But even if the Court does not exclude Mr. Rafalski's testimony, it is neither relevant nor credible. *See, e.g.*, *W.L. Gore & Assocs., Inc. v. Medtronic, Inc.*, 874 F. Supp. 2d 526, 540 (E.D. Va. 2012), *aff'd*, 530 F. App'x 939 (Fed. Cir. 2013) ("To grant JMOL under Rule 52(c), a district judge must ***weigh the evidence*** and ***resolve credibility***.").

As noted, the exclusive basis for Plaintiffs' assertion that nearly 40% of Defendants' shipments into Cabell/Huntington were improper is Mr. Rafalski—and, in particular, his Method B.[13] Method B effectively imposes for all time a monthly cap that can never exceed the largest order placed in the first six months of ordering, no matter how long ago that was or whether circumstances have changed over time. *See* 5/26 Tr. (Rafalski) at 89:10–16, 241:8–25. While Plaintiffs assert that Method B was "approved by the D.C. Circuit in *Masters*," Opp. 43, Mr. Rafalski admitted that: he preferred a different methodology that generated even more outlandish estimates, *see* 5/26 Tr. at 219:10–24, his methodologies are only "stylized illustrations," *see id.* at 222:1–4, they do not "precisely implement any Suspicious Order Monitoring System used in the real world," *see id.* at 220:14–19, and they do not mirror the systems actually discussed in *Masters*,

[13] Plaintiffs make no effort whatsoever to defend Mr. Rafalski's Method A, which resulted in the utterly implausible conclusion that upwards of 90% of Defendants' orders were improper. In addition, Plaintiffs fail to reconcile their apparent abandonment of Method A with Mr. Rafalski's testimony that it generated the "right" number of flagged orders. *See* 5/26 Tr. (Rafalski) at 219:10–24.

see id. at 238:13–21 (claiming that Method B was "similar" to *Masters* but admitting that there were "difference[s]").

Mr. Rafalski further admitted that he:

- created his methodologies for purposes of litigation, 5/26 Tr. at 222:11–13;
- never used his methodologies while he was at DEA, 5/26 Tr. at 222:5–10;
- never recommended that DEA or others use them, 5/26 Tr. at 222:21–223:11;
- never attempted to have them published or peer-reviewed, 5/26 Tr. at 223:12–17;
- never used them for any purposes other than as a paid expert witness in litigation, 5/26 Tr. at 223:18–21;
- is unaware of anyone in the real world ever adopting them, 5/26 Tr. at 220:14–19;
- did not "actually review any of the orders" captured by his flagging methodologies before rendering his opinions, 5/26 Tr. at 214:13–15, 215:1–7;
- did not know what percentage of the orders he identified "were actually investigated and … cleared" by Defendants, 5/26 Tr. at 228:21–6; and
- was not "aware of any pills that were shipped by [Defendants] that ended up filling a prescription that was dispensed other than in response to a licensed prescriber writing a prescription," 5/26 Tr. at 131:6–10.

These admissions are fatal to the reliability and credibility of Mr. Rafalski's flagging opinions.

Several additional factors further undermine those opinions and their relevance to this case.

First, Mr. Rafalski admitted that his flagging methodologies ***do not identify orders that meet the regulatory definition of "suspicious orders"***:

> Q…. Do you know how many of these tens of millions of [flagged] orders should have been reported to the DEA as suspicious?
>
> A. No, I do not.

5/26 Tr. at 229:24–230:2. Given Mr. Rafalski's express disavowal of the claim that his flagged orders were suspicious, his methodologies are entirely irrelevant to the case.

Second, Mr. Rafalski acknowledged that, during the period covered by his analyses, "legitimate" prescribing of opioids increased significantly. 5/26 Tr. at 242:6–11, 244:7–13. Yet his methodology, by design, ignored all real-world changes that affect distribution levels, *see id.* at 241:8-12, including shifts in medical need, increases in the DEA quota, population shifts, and other demographic changes, *id.* 241:17-25, 245:9-12; *see also id.* at 242:1-5 (admitting that he could not identify any generally accepted methodology "that ignores entirely what the medical community is doing in terms of increased legitimate prescriptions"). The testimony could not be clearer:

> Q…. Method B does not adjust threshold levels at all based on whether doctors are making the judgment to legitimately prescribe more or less prescription opioids, correct?
>
> A. That's correct, Your Honor.
>
> ***
>
> Do you know how many flagged orders you would generate if you did take changes in prescribing or changes in the quota and used them to adjust your maximum?
>
> A. No, I do not.

5/26 Tr. at 242:21–243:13, 247:20–23. Accordingly, and contrary to the suggestion in Plaintiffs' brief, Mr. Rafalski's methodology was not designed to identify shipments in excess of the amounts needed to respond to increased levels of good-faith prescribing by doctors.

As a result of Mr. Rafalski's failure to consider the real-world impacts of increased legitimate prescribing, he was left unable to say how many patients with cancer, or recovering from surgery, or dealing with end-of-life pain would have been deprived of vital medicines if Defendants had, in fact, refused to ship all of the orders identified by his flagging methodologies. 5/26 Tr. at 217:2–218:14. When the dominant driver of increased opioid shipments was an

increase in good-faith prescribing—as Mr. Rafalski himself admitted[14]—his failure even to consider that critical fact renders his opinions incredible and irrelevant. 5/26 Tr. at 245:4-8 (admitting that his methodology would flag a large number of prescriptions "just by normal growth in prescriptions").

Third, the testimony of Mr. Rannazzisi further undermined Mr. Rafalski's flagging methodologies. According to Mr. Rannazzisi, it is not appropriate to identify a "suspicious order" by applying an overly mechanical numerical threshold that is entirely untethered from real-world events. 6/8 Tr. at 111:11–24, 183:22–184:2; 6/9 Tr. at 81:11–13 ("A suspicious order is not just, oh, it's over the threshold. It could be over threshold because it's next to a cancer center or palliative care center, a hospital."). Yet that is precisely how Mr. Rafalski's flagging methodologies all work: they exclude all orders above different numerical thresholds without regard to any real-world events. 5/26 Tr. at 84:12–95:21, 96:10–16, 97:7–12, 231:9–14. Mr. Rannazzisi also testified that, if there is proper reporting, "the volume of suspicious orders that should come in is ***not a huge quantity of orders***. It shouldn't be like boxes of orders." 6/7 Tr. at 219:15–17 (emphasis added). That testimony is flatly inconsistent with Mr. Rafalski's flagging methodologies, which purported to identify literally ***tens of millions of orders*** as suspicious. 5/26 Tr. at 96:17–97:6.

[14] Mr. Rafalski agreed with DEA's assessment that "the overwhelming majority of American physicians who prescribe controlled substances do so for legitimate medical purposes," and that "the overwhelming majority of physicians who prescribe controlled substances do so in a legitimate manner that will never warrant scrutiny by federal or state law enforcement officials." *See* 5/26 Tr. (Rafalski) at 120:21–121:9. Mr. Rafalski further agreed with Mr. Rannazzisi's assessment that 99% of doctors prescribe opioids for legitimate medical purposes, *id.* at 121:13–19, and testified that the vast majority of doctors are trying to do the right thing, *id.* at 117:23–118:2.

In short, Plaintiffs' ***only*** evidence that Defendants improperly shipped "tens of millions" of orders into Cabell/Huntington was the testimony of Mr. Rafalski. But the flagging methodologies used by Mr. Rafalski to arrive at that figure (1) did not actually identify suspicious orders, (2) were not used in the real world by DEA or anyone else, and (3) intentionally ignored the fact that orders were increasing because legitimate prescribing was increasing. Accordingly, even if admitted, the Court should not credit Mr. Rafalski's flagging methodologies as a sufficient basis on which to conclude that Defendants shipped a meaningful number of suspicious orders in Cabell/Huntington. And absent Mr. Rafalski's flagging testimony, there is simply no evidence in the record that any of Defendants' shipments into Cabell/Huntington were improper in any way.

4. Plaintiffs' Assertion That Opioid Availability Leads to Opioid-Related Harms Is Irrelevant.

Plaintiffs devote a significant portion of their opposition to arguing that "the oversupply of prescription opioids fueled the opioid epidemic." *E.g.*, Opp. 14. But that proposition is no answer to Defendants' proximate causation arguments.

Plaintiffs rely principally on the testimony of Dr. Keyes to argue that there is a "'causal association between the supply of prescription opioids in Cabell/Huntington and the increase in opioid-related harms.'" Opp. 13. But Dr. Keyes made clear that when she refers to "supply," she is referring to opioid pills that are out in the community and being used or abused by individuals—*e.g.*, pills that have ***already left*** the closed system of distribution and are being consumed by end-users. 6/14 Tr. (Keyes) at 10:20-25. Dr. Keyes, moreover, acknowledged that the increase in opioid availability was itself caused by an increase in the number of prescriptions written by doctors. 6/14 Tr. at 82:19–22 ("the opioid crisis ***would not have occurred*** if prescribing opioids had not become standard practice in managing acute and chronic pain").

In short, there is no dispute of an association between opioid availability and opioid-related harm. Nor, for purposes of this motion, does it matter whether or not the relationship between opioid "supply" and opioid-related harms is causal. This is because Plaintiffs have not proven that ***Defendants' wrongful conduct*** was a proximate cause of the alleged oversupply. Absent evidence that Defendants were a legal cause of the increase in opioid availability in the first place, Defendants cannot be charged with the adverse consequences that Plaintiffs say flowed from the increased availability of opioids in the community.

CONCLUSION

Defendants are entitled to judgment because Plaintiffs have failed to prove any wrongdoing by a Defendant that was a proximate cause of the injuries underlying Plaintiffs' claims.

Dated: August 11, 2021

Respectfully Submitted,

McKesson Corporation
By Counsel:

/s/ Timothy C. Hester
Timothy C. Hester
Christian J. Pistilli
Laura Flahive Wu
Andrew P. Stanner
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street NW
Washington, DC 20001
Tel: (202) 662-5324
thester@cov.com
cpistilli@cov.com
lflahivewu@cov.com
astanner@cov.com

/s/ Paul W. Schmidt
Paul W. Schmidt
COVINGTON & BURLING LLP
The New York Times Building
620 Eighth Avenue
New York, New York
Tel: (212) 841-1000
pschmidt@cov.com

/s/ Jeffrey M. Wakefield
Jeffrey M. Wakefield (WVSB #3894)
jwakefield@flahertylegal.com
Jason L. Holliday (WVSB #12749)
jholliday@flahertylegal.com
FLAHERTY SENSABAUGH BONASSO PLLC
P.O. Box. 3843
Charleston, WV 25338-3843
Telephone: (304) 345-0200

AmerisourceBergen Drug Corporation
By Counsel:

/s/ Gretchen M. Callas
Gretchen M. Callas (WVSB #7136)
JACKSON KELLY PLLC
Post Office Box 553
Charleston, West Virginia 25322
Tel: (304) 340-1000
Fax: (304) 340-1050
gcallas@jacksonkelly.com

/s/ Robert A. Nicholas
Robert A. Nicholas
Shannon E. McClure
Joseph J. Mahady
REED SMITH LLP
Three Logan Square
1717 Arch Street, Suite 3100
Philadelphia, PA 19103
Tel: (215) 851-8100
Fax: (215) 851-1420
nicholas@reedsmith.com
smcclure@reedsmith.com
jmahady@reedsmith.com

Cardinal Health, Inc.
By Counsel:

/s/ Enu Mainigi
Enu Mainigi
F. Lane Heard III
Jennifer G. Wicht
Ashley W. Hardin
WILLIAMS & CONNOLLY LLP
725 Twelfth Street NW
Washington, DC 20005
Telephone: (202) 434-5000
Facsimile: (202) 434-5029
emainigi@wc.com
lheard@wc.com
jwicht@wc.com
ahardin@wc.com

Michael W. Carey (WVSB #635)
Steven R. Ruby (WVSB #10752)

Raymond S. Franks II (WVSB #6523)
David R. Pogue (WVSB #10806)
CAREY DOUGLAS KESSLER & RUBY PLLC
901 Chase Tower, 707 Virginia Street, East
P.O. Box 913
Charleston, WV 25323
Telephone: (304) 345-1234
Facsimile: (304) 342-1105
mwcarey@csdlawfirm.com
sruby@cdkrlaw.com
rfranks@cdkrlaw.com
drpogue@cdkrlaw.com

CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that on this 11th day of August, 2021, the foregoing "REPLY MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION FOR JUDGMENT ON PARTIAL FINDINGS REGARDING PROXIMATE CAUSATION" was served using the Court's CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ Timothy C. Hester
Timothy C. Hester (DC 370707)